1. **What are the advantages and disadvantages of surveillance testing?**

Surveillance testing, in conjunction with other preventive measures, has proven itself to be an effective strategy for informing public health interventions and minimizing the spread of SARS-CoV-2. It enables wide population testing to inform school administrators of the amount of viral load and transmission within a community, providing important information to make informed decisions and revise prevention policies. The disadvantages of surveillance testing arise when a non-detected individual may have to undergo a few additional steps to retrieve his/her result. In addition, if there are too few participants partaking in surveillance testing, the data will not providing meaningful information about the population as a whole.

1. **What is pool testing?**

Pool testing means combining specimens, such as saliva, from several people and conducting one laboratory test on the combined pool of samples to detect SARS-CoV-2, the virus that causes COVID-19.

Pooled testing (also known as “batch testing” or “group testing”) for SARS-CoV-2 is a process where portions of individual samples are combined into a single sample or “pool,” which is then tested together as one RT-PCR test (rather than testing samples individually).

Pooled PCR testing for surveillance of SARS-CoV-2 can play a key role in identifying and responding to both asymptomatic and pre-symptomatic cases on a regular basis without the supply and logistical strain of individual diagnostic testing.

1. **Do we need to submit multiple samples for each step in the process to determine the infected individual within the pool?**

The SalivaClear solution requires only one sample to be submitted into a single collection tube from each individual. The samples are pooled together at the lab once they arrive. All stages of the testing protocol, from surveillance to individual diagnostic tests, are performed from the one sample submitted for that one test date.

1. **What are possible test results categories of the SalivaClear? What does each category mean?**

1. Detected - Results are indicative of the presence of SARS-CoV-2 RNA. Detected results do not rule out bacterial infection or co-infection with other viruses.
2. Not Detected - Results do NOT preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
3. Inconclusive - Results are indicative of the presence of SARS-CoV-2 RNA that does NOT meet the limit of detection. A confirmatory test is recommended 48-72 hours from the prior test. All positive pools are retested in sub-pools of 2 people.
4. Invalid - The samples provided were not tested and no result was obtained. Either the sample quality was poor or there was not sufficient sample volume for testing.

**EXPLANATION OF RESULTS**

|  |  |
| --- | --- |
| **Result Appearing on the Portal:** | **Explanation of Result** |
| **COVID-19 DETECTED** | If the virus causing COVID-19 is detected in your pool, then at least one sample within the pool has the virus. Each individual sample in the positive pool is then retested to identify the presumptive positive sample barcode. |
| **COVID-19 NOT DETECTED** | Ifthe virus causingCOVID-19 is not detected in your pool, each of the samples within that pool is considered negative and no further testing is required. |
| **INCONCLUSIVE** | If your testing pool results are INCONCLUSIVE, the test cannot confidently determine the presence or absence of the coronavirus in the pooled sample. An inconclusive pooled result is treated as presumptive positive and all samples from the inconclusive pool will be reflexed or (retested) to conclude a definitive pooled result. |
| **INSUFFICIENT** | If your testing pool results are INSUFFICIENT, one or more samples submitted in the pool was non-optimal due to insufficient saliva volume in the tube. Insufficient samples will be indicated individually and does not require resampling of the entire pool. |
| **INVALID** | If your testing pool results are INVALID, one or more samples submitted in the pool was non-optimal and could not be put through the testing due to quality issues with the samples. Any sample that arrives at the laboratory in any of the following conditions will not be processed: * Insufficient quantity (volume) of liquid saliva in the tube (below 1.0 mL).
* Too much liquid saliva in the tube (above 1.5 mL).
* Contamination
* Sample collection tube is empty.

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| **IN PROGRESS** | Samples have been received in the lab. Testing is in progress AND is not complete. Testing may have been performed but the proper controls were not obtained and therefore a repeat test is required. |

1. **How quickly are results available?**

A.  Stage 1 - Surveillance Pool Test Results

Available usually within 6-8 hours upon receipt of samples in the lab; guaranteed within 24hrs.

B.  Stage 2 - Subpool Test Results (pools of 2-3 samples)

Available usually within 6-8 hours of the COVID-19 detected pool test result (stage 1); guaranteed in 12hrs.

C.  Stage 3 - Individual Diagnostic Test Result Release

Available following physician review of the test results. Depending on the timing (after 8pm), it may take up to 8 hours for the results to be reviewed and released.

1. **Does Mirimus directly report individual diagnostics test results?**

No. If a surveillance sub-pool retest of 2 samples is COVID-19 DETECTED, a SalivaDirect™ or similar individual diagnostic test can be performed on each sample in that sub-pool. Each individual diagnostic test and corresponding test result requires consent, demographics, health history, and a physician’s order to be completed on a third-party website.

Mirimus uses a third-party results reporting platform, Meenta.io, to collect and process the regulatory requirements for individual diagnostic test reporting for SalivaDirect™ testing.

1. **How long is the saliva sample viable for? Is it saliva stable at room temperature?**

Saliva samples are stable at room temperature without any buffer or refrigeration required for storage or transport.

1. **If an individual who has recovered from COVID-19 is in a pool, is there a possibility of that pool coming up as a positive?**

It is not recommended that a previously positive person be tested again by molecular testing within 60-90 days of initial recovery.

1. **If an individual has been vaccinated, should they still get tested?**

People who have received mRNA COVID-19 vaccine, should continue to get tested. The vaccine will not affect SARS-CoV-2 viral test (PCR or antigen tests results). Because the vaccine does not contain the live virus, it cannot cause you to test positive on viral tests, which are used to see if you have a current infection.

  It is important to follow public health guidelines to help you and others stay healthy, even after you get vaccinated. If you have additional questions, please visit your state or local health department’s website, or refer to the CDC for more information.

1. **Does Mirimus keep saliva samples after the pool testing has concluded and results have been reported?**

No, Mirmius stores samples for only 72hrs from receipt and does not keep negative saliva samples after the test results are reported. We work with a company called Stericycle, who are experts in biohazardous waste disposal to safely sterilize the biohazardous waste and incinerate it. Due to our testing volume, Stericycle disposes of samples from Mirimus daily. Positive samples may be stored for additional quality control testing and further testing, should the local or state Department of Health request the sample. Samples are stored in the laboratory with only barcodes and no patient identifying information.

1. **What test system is used for SalivaClear testing?**

Mirimus uses the Thermo Fisher TaqPath COVID-19 Combo Kit for pool testing and SalivaDirectTM for individual diagnostic testing. It is a fast, highly sensitive multiplex diagnostic solution that contains the assays and controls needed for the real-time PCR detection of RNA from the SARS-CoV-2 virus. Thermo Fisher TaqPath COVID-19 Combo Kit received emergency use authorization (EUA) from the U.S. Food and Drug Administration on March 13, 2020, and SalivaDirectTM received FDA EUA on August 15, 2020.

**12. What is considered a good, high-quality sample for testing?**

Samples should consist of passive drool and be devoid of phlegm and viscous mucous. We use a simple self-collection method that is composed of a 2 mL cryovial and saliva collection aid (straw).  The saliva straw fits into a cryovial and the testing individual deposits 1 mL of saliva (not bubbles) through the straw into the vial. 1 mL of saliva is required for pool testing, subpool testing, and individual diagnostic testing.

1. **Are there any controls to avoid false positives and negatives?**

Mirimus SalivaClear testing uses a two-staged test, therefore all specimens reported as “Detected” are tested twice before reporting. This helps to avoid false positives. The PCR test is one of the most sensitive tests that makes millions of copies of the viral RNA for detection; this helps to avoid any false negatives.